DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 7, 2015

Endophys, Inc.
Ronald Warren
Regulatory Consultant For Endophys, Inc.
755 N. Mathilda, Ave.
Suite 100
Sunnyvale, California 94085

Re: K141275
Trade/Device Name: Endophys Pressure Sensing Sheath Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DXO
Dated: December 5, 2014
Received: December 9, 2014

Dear Mr. Ronald Warren,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K141275

Device Name
Endophys Pressure Sensing Sheath Kit

Indications for Use *(Describe)*
The Endophys Pressure Sensing Sheath Kit (Endophys Pressure Sensing Sheath, vessel dilator and guidewire) is intended to facilitate the introduction of diagnostic and interventional devices into the vasculature and to continuously measure blood pressure during the procedure when used with the Endophys Blood Pressure Monitor.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

510(k) Notification K 141275

GENERAL INFORMATION

Applicant:
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Dallas, TX 75201
U.S.A.
Phone: 1-214-871-3320

Contact Person:
Ronald S. Warren
Regulatory Consultant for Endophys, Inc.
Experien Group, LLC.
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U.S.A.
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FAX: 1-408-400-0865

Date Prepared: May 15, 2014

DEVICE INFORMATION

Trade Name:
Endophys Pressure Sensing Sheath Kit

Generic/Common Name:
Catheter Introducer and Accessories

Classification:
Class II, 21 CFR§870.1340, Catheter Introducer and Accessories

Product Code:
DYB, Catheter Introducer,
DXO, Transducer, Pressure, Catheter tip

PREDICATE DEVICES

- Togo Medikit Co., Ltd. Super Sheath Introducer Sheath (K052557)
- Endologix AFX Introducer System (K120212)
- Millar Instruments, Inc. Mikro-Cath (K093111)
- Acist Medical Systems Rapid Exchange (RXi) System and Navvus Catheter (K132474)

510(k) SUMMARY

INDICATION FOR USE

The Endophys Pressure Sensing Sheath Kit (Endophys Pressure Sensing Sheath, vessel dilator and guidewire) is intended to facilitate the introduction of diagnostic and interventional devices into the vasculature and to continuously measure blood pressure during the procedure when used with the Endophys Blood Pressure Monitor.

PRODUCT DESCRIPTION

The Pressure Sensing Sheath ("PSS") is an introducer sheath with an integrated fiber optic pressure transducer. The PSS is provided with a dilator and a guidewire, which together make up the Endophys Pressure Sensing Sheath Kit ("PSS Kit"). The PSS Kit is intended to be used with the Endophys Blood Pressure Monitor ("BPM"), which connects to the PSS and displays the blood pressure measurements. Together with the BPM, the PSS is used to continuously monitor patient blood pressure during procedures requiring vascular access.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the indications for use for the PSS Kit. Furthermore, the PSS Kit has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as do the predicate devices. The differences in technological characteristics have been analyzed and addressed through testing. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Endophys Pressure Sensing Sheath Kit is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary testing was conducted on the PSS Kit to support a determination of substantial equivalence to the predicate devices. Testing of the PSS Kit included the following:

- Design verification testing
- Sterilization validation
- Biocompatibility testing
- Shelf life and packaging testing
- In vivo testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the PSS Kit meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates that the PSS Kit does not raise new questions of safety or effectiveness when compared to the predicate devices.

CONCLUSION

The PSS Kit contains a catheter introducer sheath with an integrated fiber optic pressure transducer, a dilator, and a guidewire for standard interventional procedures. The PSS Kit has the same intended use, patient population, and anatomical sites as well as similar technological characteristics as do the predicate devices. The differences in technological characteristics have been analyzed and addressed through testing. As such, the PSS Kit is substantially equivalent to the predicate devices.

SUMMARY

The PSS Kit is substantially equivalent to the predicate devices.